

Study Protocol and Statistical Analysis Plan

Official Title: Web-based High School Media Literacy for Healthy Relationships

Brief Title: Evaluation Study of the Online High School *Media Aware* Program

ClinicalTrials.gov ID: NCT04035694

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1. Purpose of the research project (e.g., Specific aims)

Adolescents are at risk for unhealthy sexual and relationship outcomes. Approximately 41% of high school students in the U.S. have had sex, and 43% of sexually active youth did not use a condom during their last sexual intercourse. Engaging in risky sexual behaviors can have serious consequences for adolescents. For example, approximately half of the 20 million new STI cases each year are among people between the ages of 15 and 24, and the U.S. has one of the highest teen birth rates among comparable countries. Adolescents are also at risk for sexual assault and dating violence. Ten percent of female high school students reported being forced to have intercourse against their will, and 16% of female high school students who had dated someone in the previous year reported being forced to engage in sexual acts that they did not want to by a person they were dating. Additionally, in a study among the almost 70% of high school students who had dated in the previous year, 10% reported experiencing physical dating violence. These findings suggest that comprehensive sexual health programs that include not only discussions of STIs, pregnancy, and contraception, but also healthy relationships, consent, and dating violence are needed.

Media literacy education (MLE) is an effective intervention for changing adolescent risk behavior outcomes. MLE has been shown to be an effective intervention for changing risky health behavior outcomes including those related to the use of substances, body image issues, and sexual health. Furthermore, teachers have reported that MLE is an easier avenue for teaching about sexual health than traditional sexual health education methods because it provides an engaging and neutral vehicle for discussing attitudes and knowledge about sex. Despite evidence regarding the impact of media on adolescent sexual health and the effectiveness of MLE, high schools do not systematically teach media literacy and most comprehensive sexual health curricula do not address the influence of media on adolescent sexual decision making.

A web-based MLE program for high school students, *Media Aware*, was developed and tested in a Phase I study. *Media Aware* is designed to provide students in 9th and 10th grade classrooms with sexual health knowledge, media literacy skills, and the skills to make healthy decisions about sexual activity. This Phase II RCT will allow us to evaluate the effects of *Media Aware* regarding student sexual health and provide insight into the sustainability of positive attitudinal and behavioral outcomes over time.

The specific aim of this study is to:

- i. Conduct a pretest-posttest RCT with a three-month follow-up to investigate the sustainability of positive outcomes in students in the intervention group and to examine if behavioral indicators improve over time compared to students in the delayed intervention group and to assess the effectiveness of the program implementation using teacher feedback and analyses of program process data.

2. Study Procedures (e.g., data collection, intervention implementation)

- a. Approximately 16 health education teachers (one per school) who teach 9th or 10th graders will be invited to participate in the study with up to five of their 9th or 10th grade health education classrooms.

- b. Participating teachers will be asked to endorse an online consent form, if they have not already.
- c. High schools will be randomly assigned to condition (intervention or delayed intervention) after teacher consent and school approval is obtained.
- d. All participating teachers will receive access to teacher resources, the dashboard, and *Media Aware*. Teachers will then be asked to review the *Media Aware* program and associated teacher resources.
- e. Control teachers will be asked to refrain from teaching *Media Aware* until after the follow-up.
- f. A member of the project staff or the classroom teacher will introduce the study to students in the participating classrooms (intervention and delayed intervention) using a script and invite students to participate (complete three questionnaires).
- g. Study permission forms will be distributed to students.
- h. Students will be instructed to review the study forms with their parents, indicate whether they wish to participate or not, and return to school with a signed copy of both the forms, regardless of their decision to participate.
- i. Teachers will collect and store the parental permission and student assent forms in a secure place until a member of the project staff is present to collect them. Alternately, they will mail them to the iRT office with a pre-addressed envelope provided by the project staff. Teachers will be instructed about storage by a member of the research staff.
- j. If over 80% of the eligible classroom students return/submit their parental permission forms/youth assent forms (either marked “yes” or “no”), the teacher will receive a \$30 incentive per class. Teachers may receive up to \$150 (\$30/classroom).
- k. Students whose parents choose not to give permission, or students who choose not to assent even though their parents have given permission, or who simply have not returned signed forms in time (prior to the administration of the pre-test), will not participate in the research study (i.e., complete questionnaires). Students who do not have permission to receive sexual health education will also not participate in the research study.
- l. Teachers will provide alternative activities for students who are not participating in the research study during questionnaire administration. Teachers will follow school procedures for students who do not have permission to receive sexual health education while the program is being taught.
- m. Project staff member will administer the web-based pre-test questionnaires in each classroom to students with parent permission (for sexual health education and study participation) and who have assented to participate.
 - i. Project staff members will arrange the desks with space between students and provide screen shields to increase privacy during the questionnaire. They will also maintain quiet in the classroom during data collection and be available to answer questions.
 - ii. Project staff member will read from a prepared script to instruct students how to log-in and complete the questionnaire. Questionnaires will all be completed using the online service Survey Monkey.
 - iii. Students will be given an envelope with a unique identifying number inside by a project staff member. Students will navigate to the questionnaire URL and then enter their unique ID. They will use this number in place of their name on the questionnaire. After entering the number, they will seal it in the envelope and sign their name across the seal. Project staff members will collect the envelopes and

- keep them secure until they can be stored securely at the iRT office in a locked cabinet.
- iv. Students will complete the web-based questionnaires individually. Paper-based questionnaires can also be provided, if necessary. If paper-based questionnaires are used, they will be collected and stored securely by a project staff member until they can be stored securely at the iRT office in a locked cabinet.
 - v. The questionnaire should take less than one class period to complete. Students will receive a small incentive for their participation.
- n. The intervention group will complete the *Media Aware* program over approximately the next four health class periods.
 - o. The delayed-intervention group will receive their regular health education lessons in their health classes. Teachers in the delayed-intervention group will be asked to refrain from teaching any topics related to sexual health or media literacy from the pre-test through the completion of the follow-up.
 - p. Approximately four health class periods after the pre-test questionnaire is completed, a project staff member will administer the web-based post-test questionnaires in each classroom to participating students.
 - i. Project staff members will arrange the desks with space between students and provide screen shields to increase privacy during the questionnaire. They will also maintain quiet in the classroom during data collection and be available to answer questions.
 - ii. A project staff member will read from a prepared script to instruct students how to log-in and complete the questionnaire.
 - iii. Project staff members will return the sealed ID envelopes to students. Students will open the envelope and enter their number on the questionnaire. They will seal the number in a new envelope and sign their name across the seal once again. Project staff member will collect the opened envelopes and sealed envelopes and keep them secure at the iRT office in a locked cabinet. The opened envelopes will be shredded at school or upon return to the iRT office.
 - iv. Students will complete the web-based questionnaires individually. Paper-based questionnaires can also be provided, if necessary. If paper-based questionnaires are used, they will be collected and stored securely by a project staff member until they can be stored securely at the iRT office in a locked cabinet.
 - v. The questionnaire should take less than one class period to complete. Students will receive a small incentive for their participation.
 - q. Sometime after students have completed the program, participating intervention teachers will be asked to complete the web-based Consumer Satisfaction Questionnaire (CSQ) on their own time. The CSQ will allow teachers to provide feedback on their experiences implementing the program. Teachers will receive a unique email link to a questionnaire using the iRT Data Collection System. Teachers will receive a total of \$100 for reviewing the program and teacher resources and for the completion of the CSQ.
 - r. Approximately three months after the post-test, project staff members will administer the final web-based questionnaire to students.
 - i. Project staff members will arrange the desks with space between students and provide screen shields to increase privacy during the questionnaire. They will also maintain quiet in the classroom during data collection and be available to answer questions.

- ii. Project staff member will read from a prepared script to instruct students how to log-in and complete the questionnaire.
- iii. Project staff members will return the secret number envelopes to students. Students will open the envelope and enter their number on the questionnaire. This time, a project staff member will collect the separated numbers and envelopes and shred them upon returning to the iRT office. The questionnaire should take less than one class period to complete.
- iv. Students will complete the web-based questionnaires individually. Paper-based questionnaires can also be provided, if necessary. If paper-based questionnaires are used, they will be collected and stored securely by a project staff member until they can be stored securely at the iRT office in a locked cabinet.
- v. The questionnaire should take less than one class period to complete. Students will receive a small incentive for their participation. If a student has completed all three questionnaires will also be entered in a \$50 gift card classroom drawing, which will be conducted at the conclusion of the follow-up questionnaire.
- s. Teachers in the delayed intervention group will enroll their students the *Media Aware* program after the students complete their follow-up questionnaire. Teachers will be asked to complete the CSQ after they use the *Media Aware* program with their students, and review the program. Teachers will receive a total of \$100 for reviewing the program and teacher resources and for the completion of the CSQ.

3. Brief description of proposed analyses

Preliminary Analyses. Psychometric and descriptive analyses will be conducted to study the reliability, validity, and distributions of key variables. The impact of random assignment on producing equivalent groups between conditions will be evaluated using tests of a series of single factor, condition (intervention, delayed-intervention) random effects ANOVA models estimated for each variable with a random intercept at the school level. Missing data will be examined at each time point and handled in each outcome analysis with an appropriate imputation method and estimates and standard errors will be adjusted for imputations, if warranted (Schafer, 1997).

Analyses. First, process data obtained from the LMS will be examined. Usability Analyses: The effectiveness of program implementation will be evaluated based upon the average percentage of lessons successfully completed (completed >80%). The length of time that students take to complete the program will be examined to see if the majority of students can complete the program in the allotted time frame (i.e., 4 hours spread over approximately 4 days). Satisfaction Analyses: Open-ended feedback from teachers and students on their experiences with the program will be examined to see if the teacher resources and dashboard impacted program implementation. Consumer satisfaction with the program will be achieved if scores average 2.5 or above on 80% of the 4-pt. Likert scales. Outcome Analyses: The immediate and short-term effectiveness of *Media Aware* for improving student outcomes will be examined. HLM (with random intercept at the school level) will be used to account for conditional non-independence in outcome measures at post-test and follow-up using SAS MIXED and will examine multiple observations over time. The model for the mean of each outcome will contain level 1 fixed effects representing the influence of (1) the student's pretest score and (2) gender and level 2 fixed effects of condition. Student variables found to be nonequivalent between groups will be

included as covariates in these models. The effect sizes will be calculated by dividing the appropriate contrast parameter by the sample standard deviation of the outcome. These analyses should reveal if there is a significant improvement in students' sexual health and media outcomes after having received the program as compared with the delayed-intervention group. Moderator analyses will examine subpopulations, defined by the three categorical variables of gender, relationship status, and prior sexual experience. These findings will provide evidence regarding how the effectiveness of the program varies as a function of student characteristics. Measures of program fidelity will be examined to see if differing quality or quantity of implementation can explain the findings.

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COVID-19 data collection protocol

In response to major disruptions in daily and school life as a result of COVID-19, and in the interest of public safety, we are proposing changes to the data collection procedures for this project that will allow for the collection of data without social contact between data collectors and high school students or personnel.

The current data collection and incentive distribution procedures involve project staff members administering a web-based questionnaire to students in a classroom setting in high schools and students receiving their incentives in person after the data collection is completed. The revised data collection procedure will involve students receiving a link to the web-based questionnaire in an email, whereby students can complete the questionnaires inside or outside of a classroom setting (e.g., at home) without the need for data collectors to be physically present in the classroom. Tangible incentives (i.e., water bottles and sticky notes) will be replaced with electronic gift cards that can be distributed electronically.

Below is a summary of the online data collection administration procedure:

1. Preparation/communication of study protocol change:
 - a. Research staff will contact teachers and school administration (e.g., person who gave permission for the study to take place at the school) to determine the school's status related to school closure/online instruction.
 - b. Research staff will communicate to teacher and school administrator the revisions included in this study protocol.
 - c. Research staff will send an email to students and parents/guardians communicating the revisions in the study protocol. Parent and child emails will stress the importance of allowing students to complete the post- or follow-up questionnaire in private. If parents did not include an email address on the permission form, teachers will be asked to forward the email to parents for them to forward the email to their children.
2. Data collection procedure:
 - a. Research staff will create a new set of temporary unique ID numbers for students that link to their original unique ID numbers. Only research staff will have a copy of the linking list containing both the temporary and original ID numbers.
 - b. Research staff will email students with the link to the online questionnaire along with their temporary ID number.
 - c. If schools are open or if teachers are holding synchronous online classes, teachers will instruct students to open the email and complete the questionnaire simultaneously during class.
 - d. Otherwise, the students may complete the questionnaires from home on their own time over a period of about 2 days.
 - e. Research staff will send a reminder via email on the second day. After 2 days, the questionnaire links will be closed.
3. Incentive distribution:

- a. Once data collection for a classroom is complete, research staff will email a \$5 Amazon gift card to participating students.
 - b. With respect to the classroom follow-up drawing for a \$50 Visa gift card, research staff will draw names of classroom winners from students who have completed all three questionnaires, and send them an online gift card or a physical gift card via signed-mail.
4. Data download
- a. Data will be downloaded from the online survey collector. A research staff member will use the linking list to replace the temporary ID number with the original unique ID number in the datafile. The datafile will be merged with the rest of the student data and stored on the iRT server. The online survey collector will be cleared and the temporary linking listed destroyed after the data are downloaded and verified. At this point, the temporary ID numbers are no longer linked to any data.
5. Additional possible risks associated with this change in study implementation
- a. Parents (or others) may be around during questionnaire completion and could potentially see a student's answers on the questionnaire.
 - b. Emails that contain the temporary ID numbers could be breached.
6. What steps will be implemented to minimize possible risk during study implementation?
- a. The email to parents will ask parents to respect the privacy of students when they are completing the online questionnaire. The email to students will ask students to only complete the questionnaire if they feel comfortable with their level of privacy. Students will be reminded that participation in the study is voluntary; they may choose to not answer any question they don't want to answer; and that they may withdraw from the study at any time with no penalty.
 - b. The linking list of temporary and original ID numbers will only be kept at iRT. Furthermore, once the data are downloaded, the temporary ID numbers will be replaced with the original ID number in the file. The online survey collector will be cleared and the temporary linking listed destroyed after the data are downloaded and verified. At this point, the temporary unique ID numbers are no longer linked to any data.